# PSJ3 Exhibit 497



# NACDS Strategy Combating Prescription Drug Diversion and Abuse

### Introduction

NACDS and the chain pharmacy industry are committed to partnering with law enforcement agencies, policymakers, and others to work on viable strategies to prevent prescription drug diversion and abuse. Chain pharmacies are engaged daily in activities with the goal of preventing drug diversion and abuse. However, over the past few years, DEA actions have closed prescription drug distribution centers and pharmacies, potentially leading to legitimate patients not being able to access or receive their medications in a timely manner. While an appropriate policy must empower DEA to act aggressively against individuals and companies actually engaging in diversion or having few if any meaningful controls to prevent diversion, diversion control actions must be balanced against the needs of healthcare providers to provide care to legitimate patients. We must ensure that legitimate patients receive critical medicines without interruption.

NACDS has developed this draft plan for consideration for combating prescription drug diversion and abuse. Our goal is to raise the level of engagement and interaction among industry, policymakers, regulators, and law enforcement so that we can all better address the growing problems of prescription drug diversion and abuse in a manner that also protects patient access to medications and enhances overall patient care.

### **Technology Solutions**

- NACDS is working with Surescripts to develop and implement an industry-wide solution and/or system that analyzes the data in the Surescripts network to identify physicians who may be overprescribing, as compared to a norm, and to identify patients engaged in doctor shopping. In the short-term, Surescripts will work with the NACDS Pharmacy Operations Committee and a task group of the Policy Council, using currently available data, to provide an analytical solution. In the mid-term, Surescripts and NACDS will work together to expand the data to enhance the analytical solution. The long-term goal is to develop a real-time transactional solution.
  - O To achieve these goals, Surescripts will take steps to accelerate the deployment of e-prescribing of controlled substances, including working with DEA and Boards of Pharmacy and others to potentially require that all controlled substances be prescribed electronically. It is important to note that the federal government (ONC) has implemented incentives for prescribers to adopt e-prescribing. Under Stage 1 of the incentives, presently in effect, a prescriber must transmit more than 40% of prescriptions electronically. Controlled substance prescriptions are exempt from this threshold. Under Stage 2, effective 2014, a prescriber must transmit more than 65% of all prescriptions electronically. Under the proposed rule for Stage 2, controlled substance prescriptions would continue to be exempt.
  - NACDS will work with Surescripts to flesh out the above. Once a solution is agreed upon, NACDS and Surescripts will contact DEA, ONDCP, FDA, Congress, as well as other federal and state policymakers and regulators.
- Surescripts also proposes to work with DEA to potentially require additional data, (e.g., diagnosis
  codes) on all prescriptions for controlled substances. Surescripts will work with NCPDP and other
  Standards Development Organizations (SDOs) to make the diagnosis code field mandatory for all

electronic prescriptions for controlled substances. This will provide pharmacists with additional information to assist with determining whether a drug therapy is appropriate for a patient.

• To encourage the utilization of data that pharmacies submit to prescription drug monitoring programs, NACDS will support NABP's Interconnect Program, which is connecting state prescription drug monitoring programs (PMP) to allow interstate access to PMP data.

### **Policy Statement**

NACDS will write a policy statement that will describe our efforts to prevent and reduce prescription drug abuse and diversion. The document will also describe how we collaborate with, and support others' efforts. It will be vetted with the NACDS Policy Council and NACDS Executive Committee for their approval. Among issues covered in the policy statement are those discussed below.

- Federal Advocacy
  - Orug Enforcement Administration (DEA): NACDS will pursue clarity and guidance from DEA for pharmacies as a major part of our effort. We will also seek to require DEA to consider and balance the impacts of its enforcement actions against the negative impacts on public health and patient care.
    - PDUFA lobbying: NACDS is seeking provisions in both House and Senate versions of PDUFA to require DEA and FDA to work together on reducing prescription drug diversion and abuse. Requiring DEA to work with FDA would result in better policy solutions and also would help to ensure that legitimate patient access to controlled substance medications is not jeopardized by DEA actions, as it is today.
    - NACDS will seek the creation of a bi-partisan national commission comprised of law enforcement officials (including DEA) and health care stakeholders to explore workable solutions to the problems of drug abuse and diversion. This may be pursued as part of NASPER reauthorization mentioned below. A goal will be to have this commission hold a national summit on relieving chronic pain while preventing prescription drug abuse.
  - O White House Office of National Drug Control Policy (ONDCP): NACDS will work with ONDCP to support the mission and goals of ONDCP to prevent and reduce prescription drug abuse. NACDS will encourage ONDCP to serve as the convener of the national commission mentioned above. NACDS will follow up with ONDCP from their 2011 stakeholder meeting with regard to industry work groups that ONDCP is planning to develop, as well as regarding current APhA – ONDCP collaboration.
  - NACDS will pursue the opportunity to move legislation as part of the reauthorization of NASPER, the National All-Schedules Prescription Electronic Reporting Act. NASPER provides funding to state PMPs to adopt or upgrade their PMP. A condition for funding is that the state PMP be interoperable with other state PMPs. Potential legislation to pursue as part of NASPER includes the following:
    - Creation of a bi-partisan national commission, mentioned above.
    - Increase federal funding to promote more federal prosecution of pharmacy crime.
    - Provide funding to federal and state law enforcement to better communicate and coordinate prosecution of pharmacy crime among federal, state, and local law enforcement agencies.
    - Amend laws to require mandatory minimum sentences for robberies and burglaries involving controlled substances.

- NACDS will engage Members of Congress that sit on committees that have jurisdiction over issues related to health care and prescription drug diversion and abuse. These committees include the Senate HELP, Judiciary and Finance Committees and the House Energy & Commerce and Judiciary Committees. Members of Congress that have already taken relevant action include:
  - Reps. Bono Mack and Blackburn: Sent a letter to Attorney General Holder and HHS Secretary Sebelius recognizing the potential need for clearer guidance from DEA to the health care industry and for better communication between DEA and the health care industry. Bono Mack and Blackburn want to ensure that DEA and HHS work with healthcare stakeholders and law enforcement to implement the most up-to-date and comprehensive strategies to fight prescription drug abuse and diversion.
  - Senate Finance Committee: Investigating the connection between manufacturers of pain medications and pain management groups.
  - Sens. Grassley and Whitehouse: Sent a letter to the GAO asking the GAO to study to what extent DEA's attempt to curb drug diversion and abuse inadvertently contribute to medication shortages. Sen. Grassley has requested that GAO conduct this study and report on its work by May 2013. Sen. Grassley has also requested GAO consult with relevant stakeholders including pharmacies.
  - Sen. Grassley has been pressing all 50 states to provide data on doctors that write large numbers of prescriptions for specific drugs, especially controlled substances, that are paid for by Medicaid programs.
- State Advocacy: There are a number of ways in which states are engaged in efforts to reduce the abuse and diversion of prescription drugs. NACDS will review state initiatives and legislation and assess which we should support or oppose. Potential state initiatives include:
  - Legislation/regulation to shut down pill mills.
    - Ban physician dispensing of C-II and C-III medications, or otherwise limit prescriber dispensing authority.
    - Legislation to better regulate pain management clinics.
  - Amend laws to require mandatory minimum sentences for robberies and burglaries involving controlled substances.
  - o Expand, upgrade, and interconnect PMPs.
  - o Require prescribers to review PMP information.
  - Limit prescription quantity/supply per prescription.
  - State Medicaid Medicaid patient lock-in programs are in place in North Carolina and southwestern Virginia. These programs lock-in patients to one prescriber and one pharmacy.

### Outreach:

- Prescriber groups: NACDS will engage with associations and organizations representing prescribers to develop mutually agreeable solutions, to include the development and execution of educational and joint healthcare programs on pain management and prevention of drug abuse.
- Other healthcare/retail groups: NACDS will engage with other health care and retail associations to develop and pursue solutions. These associations include:
  - o American Pharmacists Association (APhA)
  - Food Marketing Institute (FMI)
  - Healthcare Distribution Management Association (HDMA)

- National Association of Boards of Pharmacy (NABP): Support NABP "AWARXE" program, which is an information source providing authoritative resources about medication safety, prescription drug abuse, medication disposal, and safely buying medications on the Internet.
- National Association of State Pharmacy Associations (NASPA)
- National Community Pharmacists Association (NCPA)
- National Council on Prescription Information and Education (NCPIE)
- o Pharmaceutical Research and Manufacturers Association (PhRMA)
- NACDS will contact the Partnership at Drugfree.org to begin dialogue about efforts to raise awareness and educate parent, youth, and other community members.
- NACDS will develop a strategy for collaboration with insurance/health plans.
  - o NACDS will advocate for recognition of the role that pharmacists play in providing more efficient health care delivery. Pharmacist-provided services such as counseling and MTM can assist with screening patients for abuse/addiction issues; pharmacist-provided services can prevent the likelihood that a patient will fall into abuse/addiction.
  - Actions that insurance/health plans have already taken include:
    - Massachusetts Blue Cross will limit the amount of pain medication most patients can receive without prior approval by the insurer.
    - Aetna is adding capabilities to its Rx Check Program to prevent the misuse of various prescription drugs, including pain medications. The program alerts doctors to potential interactions, therapy duplications, serious complications, and other potentially inappropriate prescribing.
    - For Medicare Part D, CMS is performing utilization review and considering potential data sharing to get at overprescribing of opioids.

## **Communications Strategy:**

- After coordinating with members of the NACDS Strategic Communications Committee, NACDS developed a statement on drug diversion that the Association has used to respond to media inquiries, as well as to assist pharmacy advocates in Capitol Hill meetings. NACDS has emphasized pharmacy's zero-tolerance for drug diversion, and also pharmacy's 100-percent commitment to patient care. NACDS has noted the importance of providing necessary medications to patients a concept that should not be lost amid the focus on ensuring that prescription drugs are not diverted for illegal purposes. The NACDS statement also focuses on pharmacies' policies and procedures, pharmacies' cooperation with the Drug Enforcement Administration, and NACDS' support for related legislative initiatives.
- Once additional substantive solutions are developed, as described previously in this document, NACDS stands ready to raise awareness of them through traditional media relations techniques.
   Such techniques may include high-profile announcements, media briefings, editorial board meetings, and more. Such actions will be coordinated with the government affairs strategy to ensure that appropriate target audiences are reached.
- NACDS also will continue to work with the NACDS Strategic Communications Committee to ensure that this issue is considered in the broader context of other issues that seem to pit patient care against crime prevention. Proposals that pseudoephedrine products be moved to prescription-only

status also seem to fit into this category, and such proposals have been the subject of media inquiries to NACDS over the past year.

• To demonstrate goodwill on this issue and consistent with standard "inoculation" techniques, NACDS will publicize the Association's engagement in any programs of the Office of National Drug Control Policy and the Partnership at Drugfree.org.

